

**K221794 Vario-Cup System**Jul 20, 2022  
29 days to decisionK221794 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k221794/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Jun 21, 2022
Decision date	Jul 20, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Waldemar Link GmbH &amp; Co. KG</b>
Location	Mchenry, IL, US
Contact	Pia Mueller
510(k) history	42 submissions · 42 cleared · 1978-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>LinkBio Corp.</b>
Contact	Mateusz Leszczak

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221794/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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